
IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH

C.R. BARD, INC., a New Jersey corporation,
and BARD PERIPHERAL VASCULAR,
INC., an Arizona corporation,

Plaintiffs,

v.

MEDICAL COMPONENTS, INC., a
Pennsylvania corporation,

Defendant.

**MEMORANDUM DECISION AND
ORDER GRANTING DEFENDANT'S
MOTION TO AMEND AND DENYING
PLAINTIFFS' MOTION TO STRIKE**

2:12-cv-00032-RJS-DAO

Chief District Judge Robert J. Shelby

Magistrate Judge Daphne A. Oberg

Before the court are two separate but related motions in this heavily litigated patent infringement action. Plaintiffs C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, Bard) filed a Motion to Strike Medcomp's Inequitable Conduct Allegations in its Final Invalidity Contentions.¹ Bard argues inequitable conduct allegations cannot be asserted in invalidity contentions because they must be raised with specificity in a pleading. In response, Defendant Medical Components (MedComp) filed a Motion for Leave to File a Second Amended Answer and Counterclaims to Bard's Amended Complaint,² seeking to add a new counterclaim and an affirmative defense arising from Bard's alleged inequitable conduct. MedComp contends Bard perpetrated a fraud on the United States Patent and Trademark Office by intentionally inserting unsupported and prohibited new matter in an amendment to its parent patent application, enabling Bard to obtain an earlier, illegitimate priority date for the patents at issue in this case.

¹ Dkt. 300.

² Dkt. 321.

For the reasons explained below, Bard's Motion to Strike is DENIED, and MedComp's Motion to Amend is GRANTED.

PROCEDURAL HISTORY

On January 11, 2012, Bard filed its initial Complaint against MedComp, asserting claims for infringement of three Bard patents.³ MedComp answered the Complaint on March 14, 2012, alleging that Bard's patents were invalid and pleading counterclaims for noninfringement.⁴ On July 23, 2012, Bard filed an Amended Complaint, which remains the operative pleading.⁵ On August 3, 2012, MedComp answered Bard's Amended Complaint, reasserting its counterclaims and affirmative defenses.⁶

On October 12, 2012, the case was stayed while the patents-in-suit underwent *inter partes* reexamination before the United States Patent and Trademark Office (PTO).⁷ The stay remained in place for nearly seven years until it was lifted on October 4, 2019.⁸ Shortly after the case was reopened, the court entered a Scheduling Order, requiring that all motions to amend pleadings be filed by July 10, 2020.⁹

On June 15, 2020, MedComp first raised inequitable conduct allegations against Bard in its Initial Invalidity Contentions.¹⁰ On July 10, 2020, MedComp sought leave to amend its 2012 Answer.¹¹ MedComp sought to include additional factual detail supporting its previously

³ Dkt. 2.

⁴ Dkt. 19 (Def.'s Answer to Complaint).

⁵ Dkt. 69.

⁶ Dkt. 72 (Def.'s Answer to Amended Complaint).

⁷ See Dkt. 78 (Order Staying Case for 45 Days); Dkt. 93 (Order Staying and Administratively Closing Case).

⁸ Dkt. 161 (Order Reopening Case, Order Lifting Stay).

⁹ See Dkt. 183 (Scheduling Order).

¹⁰ See Dkt. 321 at 7.

¹¹ Dkt. 195 (Def.'s Motion to Amend).

pleaded counterclaim that Bard's U.S. Patent Nos. 7,785,302 and 7,947,022 are invalid.¹²

Specifically, MedComp's proposed amendment included allegations that the patents are invalid under 35 U.S.C. §§ 112 and 132 because Bard improperly introduced new matter before the PTO, impermissibly broadening the scope of its patents.¹³ On September 8, 2020, the court granted MedComp's Motion to Amend,¹⁴ and MedComp filed its amended answer on September 14, 2020.¹⁵

On November 25, 2020, MedComp again raised inequitable conduct, this time in its Final Invalidity Contentions.¹⁶ Bard responded by moving on December 28, 2020 to strike the inequitable conduct allegations, arguing that if MedComp wished to assert inequitable conduct, it must first move to amend its answer.¹⁷ And so MedComp did.

On January 11, 2021, MedComp sought leave to file a Second Amended Answer and Counterclaims (the SAAC) to assert a new counterclaim and affirmative defense for inequitable conduct in Bard's prosecution of the '302 patent based on alleged material misrepresentations Bard's prosecuting attorney made to the PTO.¹⁸ MedComp contends it only recently discovered evidence during fact discovery to support the proposed amendment based on the depositions of a senior Bard executive, Kelly Powers, and Bard's outside patent prosecution counsel, Todd Wight.¹⁹ Bard argues MedComp has not demonstrated good cause to amend after the deadline

¹² *See id.* at 2.

¹³ *See id.*

¹⁴ *See* Dkt. 206.

¹⁵ Dkt. 207 (Amended Answer).

¹⁶ *See* Dkt. 321 at 7.

¹⁷ Dkt. 300 at 2.

¹⁸ Dkt. 321 at 2.

¹⁹ *Id.* at 1.

for amendments has passed.²⁰ Bard further maintains the Motion to Amend should be denied for undue delay, undue prejudice, and futility based on MedComp's failure to adequately plead the claim of inequitable conduct.²¹

DISCUSSION

Because the outcome of Bard's Motion to Strike is dependent on whether MedComp is granted leave to file the SAAC, the court will turn first to MedComp's Motion to Amend before addressing Bard's Motion to Strike.

I. MedComp's Motion to File a Second Amended Answer and Counterclaims

Federal Rules of Civil Procedure 15(a)(2) and 16(b)(4) govern where, as here, a party seeks leave to amend pleadings after the deadline for amending set in a scheduling order has passed.²² Under Rule 16(b)(4), a court-issued scheduling order "may be modified only for good cause and with the judge's consent."²³ "Good cause," as required by Rule 16, is "an arguably more stringent standard than the standards for amending a pleading under Rule 15."²⁴ The "more liberal Rule 15(a) standard"²⁵ provides that, outside of amending as a matter of course, the "court should freely give leave [to amend] when justice so requires."²⁶ "Refusing leave to amend is generally only justified upon a showing of undue delay, undue prejudice to the opposing party,

²⁰ See Dkt. 360 (Bard's Opposition to Motion to Amend) at 2–5.

²¹ *Id.* at 5–10.

²² *StorageCraft Tech. Corp. v. Persistent Telecom Sols., Inc.*, No. 2:14-cv-76-DAK, 2016 WL 3435189, at *7 (D. Utah June 17, 2016) (unpublished); see also *Bylin v. Billings*, 568 F.3d 1224, 1231 (10th Cir. 2009) ("Rule 15 governs amendments to pleadings generally, Rule 16 governs amendments to scheduling orders.").

²³ Fed. R. Civ. P. 16(b)(4).

²⁴ *Bylin*, 568 F.3d at 1231.

²⁵ *StorageCraft*, 2016 WL 3435189, at *8.

²⁶ Fed. R. Civ. P. 15(a)(2).

bad faith or dilatory motive, failure to cure deficiencies by amendments previously allowed, or futility of amendment.”²⁷

In the Tenth Circuit, district courts “have consistently applied a two-step analysis based on both Rule 16(b) and Rule 15(a) when deciding a motion to amend that is filed beyond the scheduling order deadline.”²⁸ First, the court must determine “whether the moving party has established ‘good cause’ within the meaning of Rule 16(b)(4) so as to justify allowing the untimely motion.”²⁹ Second, if the court determines that good cause has been established, it will then “proceed to determine if the more liberal Rule 15(a) standard for amendment has been satisfied.”³⁰ The court will apply this two-step procedure to MedComp’s Motion to Amend.

A. MedComp Satisfies the Good-Cause Requirement Under Rule 16(b)(4)

In its 2020 Amended Counterclaim, MedComp asserted that Bard’s ’302 patent was invalid because Bard unlawfully added new matter to its Second Preliminary Amendment to the ’954 parent Patent Application by inserting unsupported drawings—known as Figs. 52A and 52B—containing a “CT” engraving as a radiopaque indicia of power injection, even though Bard certified to the PTO that these figures were not new matter.³¹ These are the same facts that also underpin MedComp’s proposed inequitable conduct claim.³² MedComp maintains that it did not have sufficient evidence before the July 10, 2020 amendment deadline to meet the heightened

²⁷ *Bylin*, 568 F.3d at 1229 (internal quotation marks and citation omitted).

²⁸ *StorageCraft*, 2016 WL 3435189, at *8; *see also Birch v. Polaris Indus., Inc.*, 812 F.3d 1238, 1247 (10th Cir. 2015) (explaining that a party seeking leave to amend after a scheduling order deadline must satisfy both the Rule 16(b) and Rule 15(a) standards).

²⁹ *StorageCraft*, 2016 WL 3435189, at *8.; *see also Gorsuch, Ltd., B.C. v. Wells Fargo Nat. Bank Ass’n*, 771 F.3d 1230, 1241 (10th Cir. 2014) (adopting the position that “parties seeking to amend their complaints after a scheduling order deadline must establish good cause for doing so”).

³⁰ *StorageCraft*, 2016 WL 3435189, at *8.

³¹ *See* Dkt. 208 at 10–14, ¶¶ 11, 16–17, 19.

³² *See* Dkt. 321 at 4.

standard for pleading inequitable conduct.³³ It was not until December 2020, when MedComp deposited Bard's inventor, Powers, and its outside patent prosecution attorney, Wight, that MedComp obtained the evidence it needed to adequately support an inequitable conduct claim.³⁴

In response, Bard argues MedComp had all the relevant information necessary to make an inequitable conduct claim as early as June 15, 2020, when MedComp included allegations of inequitable conduct in its Initial Invalidity Contentions.³⁵ Moreover, based on the same set of facts described in the preceding paragraph, Bard argues MedComp failed to make an inequitable conduct claim in its first amended pleadings, which were properly filed before the July 10, 2020 deadline.³⁶ For these reasons, Bard contends MedComp's actions show a lack of diligence to adhere to the scheduling deadlines and do not support a showing of good cause required under Rule 16.³⁷ The court disagrees.

"The burden of proving inequitable conduct is a heavy one."³⁸ Because a claim for inequitable conduct sounds in fraud, "a patent challenger who seeks to raise inequitable conduct as a defense or a counterclaim is required to meet the heightened standard of pleading set forth in Rule 9(b) of the Federal Rules of Civil Procedure, which requires a party to 'state with particularity the circumstances constituting fraud.'"³⁹ To adequately plead "the 'circumstances' of inequitable conduct with the requisite 'particularity' under 9(b), the pleading must specify the

³³ *Id.*

³⁴ *Id.* at 5.

³⁵ *See* Dkt. 360 at 3–4.

³⁶ *Id.* at 4–5.

³⁷ *Id.* at 5.

³⁸ *Lipocine Inc. v. Clarus Therapeutics, Inc.*, No. CV 19-622 (WCB), 2020 WL 4794576, at *3 (D. Del. Aug. 18, 2020) (Bryson, J. (Fed. Cir. Judge sitting by designation)).

³⁹ *Lipocine*, 2020 WL 4794576, at *8 (quoting Fed. R. Civ. P. 9(b)); *see also Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326 (Fed. Cir. 2009) ("Inequitable conduct, while a broader concept than fraud, must be pled with particularity under Rule 9(b).") (internal alteration, quotation marks, and citation omitted).

who, what, when, where, and how of the material misrepresentation or omission committed before the PTO.”⁴⁰ Additionally, the pleading must also include “sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO.”⁴¹

Inequitable conduct is a serious claim. Indeed, “the remedy for inequitable conduct is the ‘atomic bomb’ of patent law.”⁴² The finding of inequitable conduct on any single claim “renders the entire patent unenforceable.”⁴³ To discourage parties from making routine assertions of inequitable conduct,⁴⁴ the Federal Circuit has tightened the standards for such claims.⁴⁵ And unsupported inequitable conduct claims are disfavored.⁴⁶ Given the high standards of pleading and evidentiary hurdles for inequitable conduct claims, courts regularly find that “it is not unreasonable for patent challengers to postpone raising allegations of inequitable conduct until sufficient discovery has been conducted to enable the challenger [to] confirm its suspicions and gather the evidence necessary to sustain its claims.”⁴⁷ Such is the case here.

⁴⁰ *Exergen*, 575 F.3d at 1328; *see also id.* at 1318 (“Whether inequitable conduct has been pleaded with particularity under Rule 9(b) is a question governed by Federal Circuit law.”).

⁴¹ *Id.* at 1328–29.

⁴² *Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276, 1288 (Fed. Cir. 2011).

⁴³ *Id.*

⁴⁴ *Id.* at 1289 (“The habit of charging inequitable conduct in almost every major patent case has become an absolute plague.”) (internal alteration, quotation marks, and citation omitted).

⁴⁵ *See Exergen*, 575 F.3d at 1326 (requiring inequitable conduct claims to meet the heightened pleading standard of Rule 9(b)); *Therasense*, 649 F.3d at 1290 (“This court now tightens the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public.”).

⁴⁶ *Probert v. The Clorox Co.*, 258 F.R.D. 491, 494 (D. Utah 2009), *aff’d sub nom. Probert v. Clorox Co.*, 404 F. App’x. 486 (Fed. Cir. 2010) (citing *Burlington Indus. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988)).

⁴⁷ *Lipocine*, 2020 WL 4794576, at *3; *see also Probert*, 258 F.R.D. at 494 (allowing Defendant to amend its complaint to include an inequitable conduct claim because Defendant “appropriately waited until after taking Plaintiffs’ depositions” before making the claim); *StorageCraft*, 2016 WL 3435189, at *8 (similar).

While MedComp acknowledges the deadline for amending pleadings passed on July 10, 2020, it asserts that it could not have met the heightened pleading standard for an inequitable conduct claim until after it conducted the depositions of Powers and Wight in December 2020.⁴⁸ MedComp early on suspected inequitable conduct based on Bard's publicly filed patent application documents, but it could not confirm its suspicions until fact discovery and depositions were completed.⁴⁹ This is not a unique circumstance. In fact, "it is ordinarily the case that the facts relevant to an inequitable conduct claim are within the [exclusive] possession of the patentee and persons under the patentee's control."⁵⁰ Rather than include an unsupported inequitable conduct claim in its 2020 Amended Complaint, MedComp sought to depose Wight to determine whether there was an innocent explanation for the late addition of the two figures in the patent application.⁵¹ "Given that a claim of inequitable conduct requires proof of specific intent to deceive on the part of the applicants or their representatives, it is hardly surprising that a responsible defense counsel would wish to depose those individuals before charging them with deceptive intent."⁵²

As it relates to Rule 16, MedComp's reason for delay in seeking an amendment satisfies the good-cause requirement. "Rule 16(b) does not focus on the bad faith of the movant, or the prejudice to the opposing party. Rather, it focuses on the diligence of the party seeking leave to

⁴⁸ See Dkt. 321 at 4–5.

⁴⁹ Dkt. 428 (MedComp's Reply) at 1–2.

⁵⁰ *Lipocine*, 2020 WL 4794576 at *10.

⁵¹ Dkt. 428 at 2.

⁵² *Lipocine*, 2020 WL 4794576 at *4; see also *Probert*, 258 F.R.D. at 494 ("[W]hile Defendant admits that it had suspicions about inequitable conduct upon receipt of Plaintiffs' document production, rather than filing its motion for leave to amend at that time, it appropriately waited until after taking Plaintiffs' depositions.").

modify the scheduling order to permit the proposed amendment.”⁵³ Good cause is established under Rule 16(b)(4) if the moving party shows it could not meet the scheduling deadline despite its diligent efforts.⁵⁴ Here, MedComp has demonstrated it was able to acquire the necessary evidence to raise an inequitable conduct claim only after the deadline for amending pleadings had expired.⁵⁵ Especially in light of the heightened pleading standards for inequitable conduct claims, MedComp’s decision to wait until key depositions were completed (thus ensuring it had sufficient evidence) was completely reasonable under the circumstances. MedComp then acted diligently, filing its Motion seeking leave to add its counterclaim only thirty-four days after taking Wight’s deposition.⁵⁶ MedComp has established the requisite good cause under Rule 16 for requesting leave to file the SAAC after the deadline for amending pleadings in the scheduling order.⁵⁷

Having determined that MedComp satisfies Rule 16’s good-cause requirement, the first step in the analysis is complete. The court will now turn to the second step in the analysis and explain how MedComp also satisfies the Rule 15(a) standard for amending pleadings.

B. MedComp Satisfies the Standards of Rule 15(a)

Whether to grant a party’s request to amend the pleadings pursuant to Rule 15(a) “is within the discretion of the trial court.”⁵⁸ The Rule provides a liberal standard, stating that “the

⁵³ *Georgelas v. Call*, No. 2:16-cv-00511-RJS-PMW, 2020 WL 2043535, at *1 (D. Utah Apr. 28, 2020) (quoting *Pumpco, Inc. v. Schenker Int’l, Inc.*, 204 F.R.D. 667, 668 (D. Colo. 2001)).

⁵⁴ *Id.*

⁵⁵ *Id.* at *2 (“Having acquired the information after the expiration of the deadline to add parties, Plaintiff could not have met the deadline with diligent effort.”).

⁵⁶ See Dkt. 428 at 3.

⁵⁷ See *Pumpco, Inc. v. Schenker Int’l, Inc.*, 204 F.R.D. at 668–69 (“The fact that a party learns, through discovery or disclosures, information necessary for the assertion of a claim after the deadline to amend established in the scheduling order has expired constitutes good cause to extend that deadline.”).

⁵⁸ *Minter v. Prime Equipment Co.*, 451 F.3d 1196, 1204 (10th Cir. 2006).

court should freely give leave when justice so requires.”⁵⁹ “The purpose of the Rule is to provide litigants the maximum opportunity for each claim to be decided on its merits rather than on procedural niceties.”⁶⁰ The Supreme Court explains that parties “ought to be afforded an opportunity to test [their] claim on the merits,” unless the nonmoving party can demonstrate “undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party . . . [or] futility of amendment[.]”⁶¹

Here, Bard argues MedComp’s Motion to Amend should be denied for undue delay, undue prejudice, and futility of amendment.⁶² The court will address each argument in turn.

1. Undue Delay

A party’s ability to amend its pleadings is not restricted to a particular stage in the action.⁶³ Therefore, “[l]ateness does not of itself justify the denial of the amendment.”⁶⁴ Rather, the Tenth Circuit “focuses primarily on the reasons for the delay.”⁶⁵ If the moving party “has no adequate explanation for the delay,” the court has sufficient ground to deny leave to amend.⁶⁶

Bard relies on the same argument to demonstrate MedComp’s undue delay as it advanced in its contentions under Rule 16: MedComp was aware of all the information it needed to raise an inequitable conduct claim long before the deadline to amend the pleadings expired.⁶⁷ As

⁵⁹ Fed. R. Civ. P. 15(a)(2).

⁶⁰ *Id.* (internal quotation marks and citation omitted).

⁶¹ *Foman v. Davis*, 371 U.S. 178, 182 (1962).

⁶² *See* Dkt. 360 at 5–10.

⁶³ *See Minter*, 451 F.3d at 1205.

⁶⁴ *Id.* (internal quotation marks and citation omitted).

⁶⁵ *Id.* at 1206.

⁶⁶ *Id.* (quoting *Frank v. U.S. West*, 3 F.3d 1357, 1365–66 (10th Cir. 1993)).

⁶⁷ *See* Dkt. 360 at 5–6.

previously explained, MedComp prudently waited until it had sufficient evidence to support an inequitable conduct claim before diligently seeking leave to amend its pleadings. This is an adequate reason for the delay. As noted, MedComp filed its Motion only thirty-four days after Wight's deposition was completed.⁶⁸ This is not excessive delay. The court concludes MedComp's Motion to Amend was timely filed.

2. Undue Prejudice

When deciding a motion to amend the pleadings, the most important factor "is whether the amendment would prejudice the nonmoving party."⁶⁹ "Courts typically find prejudice only when the amendment unfairly affects the defendants in terms of preparing their defense to the amendment."⁷⁰ This occurs most often "when the amended claims arise out of a subject matter different from what was set forth in the complaint and raise significant new factual issues."⁷¹ The non-moving party bears the burden of proof on the issue of prejudice under Rule 15(a)(2).⁷²

Bard argues MedComp's proposed amendment would be prejudicial because it would require Bard to take additional discovery in order to ascertain the full scope of MedComp's claims and generalized allegations.⁷³ Bard maintains this will prolong the already lengthy proceedings against its wishes to move forward to trial.⁷⁴

⁶⁸ See Dkt. 428 at 3.

⁶⁹ *Minter*, 451 F.3d at 1207.

⁷⁰ *Id.* at 1208 (internal quotation marks and citation omitted).

⁷¹ *Id.*

⁷² *Lipocine*, 2020 WL 4794576 at *6.

⁷³ See Dkt. 360 at 6–7.

⁷⁴ *Id.* at 6.

MedComp contends Bard's purported need to take additional discovery is not credible.⁷⁵ MedComp asserts Bard had actual notice MedComp would seek to amend its pleading to add an inequitable conduct claim because MedComp included this allegation in both its Initial and Final Invalidity Contentions.⁷⁶ Moreover, MedComp insists the proposed inequitable conduct claim does not alter the focus of the case because it is related to the counterclaims MedComp already pleaded in its Amended Complaint.⁷⁷ And the new facts solely involve: "(1) the sworn recollections of senior Bard personnel regarding patent prosecutions that are central to this dispute; and (2) sworn recollections regarding Bard's handling of the prosecution file containing those documents."⁷⁸

The court does not find Bard's argument regarding prejudice persuasive for two reasons. First, Bard was on notice MedComp intended to pursue an inequitable conduct claim against it since at least June 15, 2020, when MedComp first included inequitable conduct allegations in its Initial Invalidity Contentions. Although Bard argues that inequitable conduct cannot be added to a case through such contentions,⁷⁹ "[Bard] was clearly on notice that [MedComp] intended to raise the issue, and it would have been prudent for [Bard] to prepare for the possibility" that MedComp would seek leave to amend its pleadings to include the issue.⁸⁰ In addition, the inequitable conduct claim is closely related to the invalidity claim of Bard's '302 patent, which MedComp already raised in its Amended Complaint. Not only do the same facts underpin both claims, but the defenses to the invalidity claim "apply with equal force" to the inequitable

⁷⁵ See Dkt. 428 at 4.

⁷⁶ *Id.* at 5.

⁷⁷ See Dkt. 321 at 7.

⁷⁸ *Id.*

⁷⁹ See Dkt. 360 at 1.

⁸⁰ *Lipocine*, 2020 WL 4794576 at *6.

conduct claim.⁸¹ Accordingly, the inequitable conduct claim did not come as a surprise to Bard, nor is Bard unprepared to address it.⁸²

Second, the court is not convinced the addition of MedComp's inequitable conduct claim will require Bard to conduct extensive additional fact discovery. "Typically, the plaintiff in an inequitable conduct dispute has access to all the information that is pertinent to its case[.]"⁸³ The same is true here. MedComp's inequitable conduct claim is premised on the sworn recollections of senior Bard personnel and Bard's handling of its own prosecution file containing the documents relating to the patent prosecutions at issue in this case. Given that this information is primarily within Bard's control, significant additional fact discovery is unlikely. Bard will not be unduly prejudiced by allowing MedComp's proposed inequitable conduct claim.

The court concludes that Bard has failed to carry its burden of establishing it will suffer significant prejudice from MedComp's proposed amendments.

3. Futility

Bard argues that granting MedComp's Motion to Amend is futile for the following reasons: (1) MedComp's SAAC fails to meet the heightened pleading standard of Rule 9(b);⁸⁴ (2) MedComp's allegations fail to show the requisite intent of Bard to deceive the PTO;⁸⁵ and (3) MedComp did not allege facts demonstrating "but-for" materiality.⁸⁶ All three arguments fail.

⁸¹ See *Minter*, 451 F.3d at 1208–09 (finding the addition of a new claim would not prejudice the defendant because the similarities of the claims between the initial and amended pleadings included "significant overlap in the factual underpinnings and defenses").

⁸² See *Lipcine*, 2020 WL 4794576 at *6.

⁸³ *Id.* at *7 (listing cases).

⁸⁴ See Dkt. 360 at 7–8.

⁸⁵ See *id.* at 8–10.

⁸⁶ See *id.* at 10.

a. MedComp’s SAAC Meets Rule 9(b)’s Heightened Standard of Pleading

As previously explained, when “pleading inequitable conduct in patent cases, Rule 9(b) requires identification of the specific who, what, when, where, and how of the material misrepresentation or omission before the PTO.”⁸⁷ Bard argues MedComp’s generalized allegations against “Bard” and its “agents and attorneys” are insufficient to adequately plead the “who” of inequitable conduct.⁸⁸ In response, MedComp asserts it adequately identified Wight—Bard’s outside patent prosecution attorney—as the individual who made the alleged affirmative misrepresentation to the PTO.⁸⁹ The court, having carefully reviewed the proposed inequitable conduct claim in the SAAC, agrees with MedComp.

The SAAC repeatedly identifies Wight and his conduct before the PTO as the basis for the inequitable conduct claim.⁹⁰ Indeed, in Paragraph 81 of the SAAC, MedComp explicitly states, “Bard’s inequitable conduct in the prosecution of the ’302 patent stems from an affirmative misrepresentation of the prosecuting attorney, Todd Wight[.]”⁹¹ This is no generalized reference to Bard, its agents, and/or attorneys.⁹² In this example, as in many others, MedComp “name[s] the specific individual associated with the filing or prosecution” of the patent at issue, “who both knew of the material information and deliberately withheld or misrepresented it.”⁹³ This satisfies the “who” requirement under Rule 9(b).

⁸⁷ *Exergen*, 575 F.3d at 1327.

⁸⁸ Dkt. 360 at 7–8.

⁸⁹ See Dkt. 428 at 6.

⁹⁰ See, e.g., Dkt. 321-1, Ex. A (MedComp’s Proposed SAAC) ¶¶ 80, 81, 125, 127, 130, 139, 147, 163, 165, 170.

⁹¹ *Id.* ¶ 81.

⁹² See *Exergen*, 575 F.3d at 1329.

⁹³ *Id.*

Not only does MedComp’s SAAC adequately identify (who) Wight, but it also sufficiently alleges: (what) the seeking of an earlier priority date for the ’302 patent by improperly adding new material to the patent application materials;⁹⁴ (when) during the patent prosecution;⁹⁵ (where) the application for the ’302 patent;⁹⁶ and (how) by submitting false declarations to the PTO.⁹⁷

For these reasons, the court finds that MedComp’s SAAC satisfies the heightened pleading standards of Rule 9(b).

b. MedComp’s SAAC Includes Sufficient Allegations to Infer Bard’s Intent to Deceive the PTO

“[A] pleading of inequitable conduct under Rule 9(b) must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew . . . of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO.”⁹⁸ “Intent and materiality are separate requirements,” meaning that “a court must weigh the evidence of intent to deceive independent of its analysis of materiality.”⁹⁹

“Because direct evidence of deceptive intent is rare, a district court may infer intent from indirect and circumstantial evidence.”¹⁰⁰ The burden of proof rests on the party alleging inequitable conduct.¹⁰¹ Nevertheless, inequitable conduct claims are “rarely disallowed at the

⁹⁴ See, e.g., Dkt. 321-1 ¶ 163.

⁹⁵ *Id.* ¶ 122.

⁹⁶ *Id.*

⁹⁷ *Id.* ¶ 139.

⁹⁸ *Exergen*, 575 F.3d at 1328–29.

⁹⁹ *Therasense*, 649 F.3d at 1290.

¹⁰⁰ *Id.*

¹⁰¹ *Id.* at 1291.

pleading stage due to failure to adequately allege scienter.”¹⁰² MedComp need only plead sufficient facts from which it may be inferred that Wight made a material misrepresentation during the prosecution of the ’302 patent and did so with the specific intent to deceive the PTO.¹⁰³

As explained, MedComp’s inequitable conduct claim is based on the allegations that Bard, through Wight, impermissibly added new figures in an amendment to the ’954 parent patent application while representing that no new matter was introduced, and this was done with an intent to deceive the PTO. The purpose of this alleged misrepresentation was to broaden the scope of Bard’s patents and obtain an earlier, illegitimate priority date for Bard’s ports that were marked with the “CT” indicia.¹⁰⁴

Bard argues MedComp has offered no factual support that Bard’s counsel or employees knew of the falsity of the alleged material misrepresentation before the PTO.¹⁰⁵ Specifically, MedComp cannot show Wight believed his statement to the PTO—that no new matter was introduced in the ’954 application—was false.¹⁰⁶

MedComp contends it has provided robust circumstantial evidence demonstrating Bard’s intent to deceive the PTO. First, Bard had a strong commercial motivation to secure an earlier priority date for its own patents, which would exclude other competitors from using the “CT” indicia.¹⁰⁷ Second, as Bard’s longtime patent prosecution attorney, Wight understood the

¹⁰² *Lipocine*, 2020 WL 4794576 at *8 (internal quotation marks and citation omitted).

¹⁰³ *See id.* (explaining in the context of the specific facts before the court: “It is enough that the defendant plead sufficient facts from which it may be inferred that the applicant knew of withheld material information and withheld that information with the specific intent to deceive the PTO.”) (citation omitted).

¹⁰⁴ *See* Dkt. 321 at 3.

¹⁰⁵ *See* Dkt. 360 at 9.

¹⁰⁶ *Id.*

¹⁰⁷ Dkt. 321 at 9.

material he was submitting to the PTO.¹⁰⁸ Third, Wight submitted the new figures to the PTO on the same day Bard engineers emphasized the “CT” designation was a “new feature” the Bard sales team would be emphasizing.¹⁰⁹ Fourth, Wight’s deposition testimony was evasive, and he was unable to adequately explain the inclusion of the new figures in the patent application materials.¹¹⁰

It is not necessary for MedComp to demonstrate definitively at the pleading stage whether Wight believed his statement to the PTO was false.¹¹¹ Such direct evidence is rare and not required.¹¹² It is enough for MedComp to provide sufficient information from which the court may infer deceptive intent. This MedComp has done. The court finds the aforementioned allegations, in conjunction with the detailed factual allegations included in MedComp’s SAAC regarding the inequitable conduct claim, are “sufficient to support an inference of specific intent to deceive the PTO.”¹¹³

c. Bard’s Alleged Misrepresentations are an Exception to the But-For Materiality Requirement

“[A]s a general matter, the materiality required to establish inequitable conduct is but-for materiality.”¹¹⁴ When assessing the materiality of an alleged false or misrepresented statement, “the court must determine whether the PTO would have allowed the claim if it had been aware of

¹⁰⁸ *Id.*

¹⁰⁹ *See id.* at 10.

¹¹⁰ *See* Dkt. 428 at 8–9.

¹¹¹ *See Probert*, 258 F.R.D. at 495 (“Although Plaintiffs argue that each asserted basis for Defendant’s inequitable conduct counterclaim lacks material evidence in support, Defendant is not required to meet its full burden of proof at the pleading stage.”).

¹¹² *Lipocine*, 2020 WL 4794576 at *8.

¹¹³ *See id.*

¹¹⁴ *Therasense*, 649 F.3d at 1291.

the [misrepresentation].”¹¹⁵ However, there is an exception to the but-for materiality requirement in cases where “the patentee has engaged in affirmative acts of egregious misconduct.”¹¹⁶ For example, the filing of “a false affidavit or declaration is per se material.”¹¹⁷ A claim for priority is also “inherently material to patentability because a priority date may determine validity[.]”¹¹⁸ Therefore, a misrepresentation regarding priority is material regardless whether it would have “immediately affected patentability.”¹¹⁹

Bard argues MedComp has failed to plead facts within the narrow exception of but-for materiality,¹²⁰ insisting instead that MedComp must provide evidence of a deliberately planned and carefully executed scheme to defraud the PTO.¹²¹ In response, MedComp contends but-for materiality is not required because it has sufficiently pled and adequately alleged facts that Wight committed egregious misconduct by making an affirmative misrepresentation to the PTO.¹²² Moreover, MedComp emphasizes the alleged misrepresentation concerned the priority date of Bard’s patents, arguing that false claims of priority are always highly material.¹²³ The court again agrees with MedComp.

The Federal Circuit instructs that a false declaration is “per se material.”¹²⁴ A misrepresentation regarding priority is also inherently material.¹²⁵ There are no further steps in

¹¹⁵ *Id.*

¹¹⁶ *Id.* at 1292.

¹¹⁷ *Outside the Box Innovations, LLC v. Travel Caddy, Inc.*, 695 F.3d 1285, 1294 (Fed. Cir. 2012).

¹¹⁸ *Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223, 1233 (Fed. Cir. 2007).

¹¹⁹ *Id.*

¹²⁰ *See* Dkt. 360 at 10.

¹²¹ *Id.* (citing *Therasense*, 649 F.3d at 1292).

¹²² *See* Dkt. 428 at 10.

¹²³ *Id.*

¹²⁴ *Outside the Box*, 695 F.3d at 1294.

¹²⁵ *Nilssen*, 504 F.3d at 1233.

the analysis requiring a district court to find evidence of a deliberate scheme to defraud the PTO. So long as MedComp separately satisfies the “intent to deceive prong,” the exception to the but-for materiality requirement applies. As previously discussed, MedComp’s detailed factual allegations included in the SAAC provide the court with enough information to reasonably infer that Wight’s alleged statement to the PTO was a false declaration, and thus material. Bard’s futility arguments fail.

Based on the foregoing analysis, the court concludes that justice requires MedComp be allowed to file its SAAC, which will provide the maximum opportunity for the claims to be decided on the merits, as provided for under Rule 15’s liberal standard. Having so decided, the court now turns to Bard’s Motion to Strike.

II. Bard’s Motion to Strike MedComp’s Inequitable Conduct Allegations from the Final Invalidity Contentions

Bard’s Motion to Strike is based entirely on its argument that inequitable conduct allegations cannot be asserted in invalidity contentions but must be raised in a pleading with the requisite specificity.¹²⁶ Because the court grants MedComp’s request to file the SAAC for the reasons discussed above, Bard’s Motion to Strike is rendered moot.

In Bard’s Reply brief in support of its Motion to Strike, Bard insists MedComp’s Motion to Amend does not moot Bard’s motion to strike because “the allegations contained in MedComp’s proposed [SAAC] do not match the allegations in MedComp’s Final Invalidity Contentions.”¹²⁷ The court will not consider this argument as it was “not mentioned in the opening brief, much less argued, and [is] therefore abandoned.”¹²⁸ The general rule in the Tenth

¹²⁶ See Dkt. 300 at 2–3.

¹²⁷ Dkt. 361 at 3.

¹²⁸ *Reedy v. Werholtz*, 660 F.3d 1270, 1274 (10th Cir. 2011).

Circuit “is that a party waives issues and arguments raised for the first time in a reply brief.”¹²⁹

Moreover, the court’s Local Rules require that all “[r]eply memoranda must be limited to rebuttal of matters raised in the opposition memoranda.”¹³⁰ The court will not depart from these rules.

CONCLUSION

For the foregoing reasons, Bard’s Motion to Strike Medcomp’s Inequitable Conduct Allegations in its Final Invalidity Contentions¹³¹ is DENIED, and MedComp’s Motion for Leave to File a Second Amended Answer and Counterclaims to Bard’s Amended Complaint¹³² is GRANTED. MedComp is ORDERED to file the SAAC within seven (7) days of the entry of this Order. Bard is to respond within the time permitted under the Rules.

SO ORDERED this 6th day of May 2021.

BY THE COURT:

A handwritten signature in black ink, appearing to read 'RJS', is written over a horizontal line.

ROBERT J. SHELBY
United States Chief District Judge

¹²⁹ *Id.* (internal quotation marks and citation omitted).

¹³⁰ DUCivR 7-1(b)(2)(C). Here, there are no arguments raised in MedComp’s Opposition Memorandum that could be considered related to Bard’s argument of a mismatch between MedComp’s allegations in the SAAC and the Final Invalidity Contentions. *See* Dkt. 322 at 1–2.

¹³¹ Dkt. 300.

¹³² Dkt. 321.